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Randomized controlled multicentre study comparing short dental implants (6 mm) versus longer dental implants (11-15 mm) in combination with sinus floor elevation procedures. Part 1: demographics and patient-reported outcomes at 1 year of loading

Thoma, Daniel S ; Haas, Robert ; Tutak, Marcin ; Garcia, Abel ; Schincaglia, Gian Pietro ; Hämmerle, Christoph H F

Abstract: AIM To test whether or not the use of short dental implants (6 mm) results in an implant survival rate similar to long implants (11-15 mm) in combination with sinus grafting. **METHODS** This multicentre study enrolled 101 patients with a posterior maxillary bone height of 5-7 mm. Patients randomly received short implants (6 mm) (group short) or long implants (11-15 mm) with sinus grafting (group graft). Six months later, implants were loaded with single crowns and patients re-examined at 1 year of loading. Outcomes included treatment time, price calculations, safety, patient-reported outcome measures (OHIP-49 = Oral Health Impact Profile) and implant survival. Statistical analysis was performed using a non-parametric approach. **RESULTS** In 101 patients, 137 implants were placed. Mean surgical time was 52.6 min. (group short) and 74.6 min. (group graft). Mean costs amounted to 941EUR (group short) and 1946EUR (group graft). Mean severity scores between suture removal and baseline revealed a statistically significant decrease for most OHIP dimensions in group graft only. At 1 year, 97 patients with 132 implants were re-examined. The implant survival rate was 100%. **CONCLUSIONS** Both treatment modalities can be considered suitable for implant therapy in the atrophied posterior maxilla. Short implants may be more favourable regarding short-term patient morbidity, treatment time and price.

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Randomized controlled multicenter study comparing short dental implants (6mm) versus longer dental implants (11-15mm) in combination with sinus floor elevation procedures. Part 1: demographics and patient-reported outcomes at 1 year of loading

Daniel S. Thoma^a, Robert Haas^b, Marcin Tutak^c, Abel Garcia^d, Gian Pietro Schincaglia^e, Christoph H. F. Hammerle^a

Running title: short implants vs. sinus floor elevation procedures

Key words: dental implant, sinus floor elevation, sinus grafting, short dental implant, multicenter, randomized controlled clinical trial, bone augmentation, patient satisfaction, quality of life, OHIP, OHIP-49

^a Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Switzerland

^b Akademie für Orale Implantologie, Private Practice, Vienna, Austria

^c Aesthetic Dent, Private Practice, Szczecin, Poland

^d University of Santiago de Compostela, Spain

^e University of Connecticut, Farmington, USA

Address for correspondence: PD Dr. Daniel S. Thoma
Clinic of Fixed and Removable Prosthodontics and Dental
Material Science
Center of Dental Medicine, University of Zurich
Plattenstrasse 11, CH-8032 Zurich, Switzerland
Phone: +41 44 634 32 51
Fax: +41 44 634 43 05
e-mail: daniel.thoma@zzm.uzh.ch

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CLINICAL RELEVANCE

Scientific rationale for the study: implant therapy in the posterior maxilla with a limited ridge height presents challenges to the clinician. At present, a sinus floor elevation procedure to increase the ridge height in combination with the placement of long dental implants is considered the gold standard. In order to overcome limitations and disadvantages associated with this procedure, the use of shorter dental implants has been proposed to avoid extensive bone augmentation surgeries

Principal findings: Both treatment options, sinus floor elevation with long implants and short implants rendered similar outcomes at 1 year of function with respect to implant survival rates. Treatment costs, surgical time and physical disability at the day of suture removal were lower for the group with short dental implants.

Practical implications: Within the limitations of this study both treatment options can be recommended for the severely atrophied posterior maxilla.

ABSTRACT

Aim: to test whether or not the use of short dental implants (6mm) results in an implant survival rate similar to long implants (11-15mm) in combination with sinus grafting.

Methods: This multicenter study enrolled 101 patients with a posterior maxillary bone height of 5-7mm. Patients randomly received short implants (6mm) (group short) or long implants (11-15mm) with sinus grafting (group graft). Six months later, implants were loaded with single crowns and patients re-examined at one year of loading. Outcomes included: treatment time, price calculations, safety, patient-reported outcome measures (OHIP-49=Oral Health Impact Profile) and implant survival. Statistical analysis was performed using a non-parametric approach.

Results: In 101 patients, 137 implants were placed. Mean surgical time was 52.6minutes (group short) and 74.6minutes (group graft). Mean costs amounted to 941EUR (group short) and 1946EUR (group graft). Mean severity scores between suture removal and baseline revealed a statistically significant decrease for most OHIP dimensions in group graft only. At one year, 97 patients with 132 implants were re-examined. The implant survival rate was 100%.

Conclusions: Both treatment modalities can be considered suitable for implant therapy in the atrophied posterior maxilla. Short implants may be more favorable regarding short-term patient morbidity, treatment time and price.

INTRODUCTION

Implant therapy with fixed dental prosthesis (FDPs) is considered a predictable treatment option with high implant and prosthesis survival rates (Jung et al., 2012, Pjetursson et al., 2012). In the posterior region of the maxilla, primary implant placement is often difficult to achieve due to a limited ridge height following the expansion of the sinus maxillaris and vertical bone loss of the ridge after tooth extraction. Classically, two options exist to increase the ridge height in the posterior maxilla: i) vertical bone regeneration in a caudal direction (Simion et al., 2004); ii) a sinus floor elevation procedure in a cranial direction, using a transalveolar or a lateral window approach (Boyne and James, 1980, Summers, 1994). In case of a severely reduced ridge height, the latter option allows to increase the ridge height up to 14 mm (Reinert et al., 2003). While implants placed simultaneously with a sinus floor elevation procedure or staged after a healing period of 6-8 months render high survival rates, complications (e.g. membrane perforation, postoperative sinusitis, partial or complete graft failure) associated with the procedure are frequent (Nkenke and Stelzle, 2009). The results from systematic reviews, including clinical studies with the lateral window approach and simultaneous implant placement demonstrated complications to occur in up to 38% of the patients (Stricker et al., 2003) and implants to fail in up to 17% within 3 years (Pjetursson et al., 2008). In order to overcome these drawbacks and to limit the complication rate, shorter dental implants may be considered as a treatment option. This approach may offer advantages: fewer interventions, shorter treatment time, reduced costs and a lower patient morbidity. Most recently, a number of systematic reviews evaluated the survival rate of short dental implants, overall concluding that the survival rates are similar to long implants (Srinivasan et al., 2013, Annibali et al., 2012, Sun et al., 2011, Atieh et al., 2012, Telleman et al., 2011). Nevertheless, limitations such as a slightly lower survival rate in soft bone or in the posterior maxilla were reported (Telleman et al., 2011). Scientific evidence is scarce on short dental implants placed in the posterior maxilla. In addition, in most clinical studies short implants were splinted to

longer ones (Renouard and Nisand, 2005, Felice et al., 2011). In summary, both treatment options for the posterior maxilla, sinus floor elevation procedures with long implants and short dental implants might have their own limitations and advantages (Corbella et al., 2013). From a patient perspective implant survival rates and marginal bone level changes are not the only relevant outcome parameters. Thus, costs, treatment time and morbidity associated with the procedures also play a crucial role.

The primary aim of the present multicenter study was therefore to test whether or not the use of short dental implants (6mm) results in an implant survival rate similar to long implants (11-15mm) in combination with sinus grafting. Secondary aims of the study included patient-reported outcomes, safety, treatment time and price calculations associated with the two treatment options.

MATERIALS AND METHODS

Study design

The present study was designed as an open, prospective, randomized, controlled multicenter study. Prior to the start of the study, an investigator calibration meeting was held to aim for consensus regarding the study protocol. Following approval by the respective local ethics committees in all 5 centers, 101 patients were recruited for the study. Informed consent was obtained from all patients prior to the start of the investigation. A block randomization sequence was used to provide an equal distribution of subjects treated with either short implants (group short) or long implants in combination with a sinus floor elevation procedure (group graft). The randomization was performed at the day of surgery following flap elevation using a sealed envelope containing the allocated treatment. A detailed overview of the study design is given in Figure 1 and Table 1.

Clinical procedures

Screening (SC)

Subjects with partial edentulism in the posterior maxilla were considered for the treatment and further screened using appropriate clinical and radiographic examinations (e.g. dental panoramic x-ray, peri-apical x-ray, CBCT, CT). In addition, a questionnaire (OHIP-49) was filled out by the patients to assess patient-reported outcomes measures assessed as severity scores. The following inclusion criteria were applied:

- signed informed consent
- age between 20 and 75 years at enrolment
- systemically healthy and no uncontrolled pathologic processes in the oral cavity
- partial edentulism in the posterior maxilla (since at least 4 months)
- need of 1-4 implants in either side of the posterior maxilla (premolar and molar region)
- presence of neighboring tooth/teeth to the planned implant site(s) with absence of pathology or excessive bone loss
- presence of natural tooth/teeth, partial prosthesis and/or implants in the opposite jaw in contact with the planned crown/s
- ridge height between 5 and 7 mm and ridge width ≥ 6 mm

Implant placement (IP)

Implant therapy was performed according to the manufacturer's recommendations. In addition, the duration of the surgery was calculated in minutes. Preoperatively, patients were pre-medicated with antibiotics and analgesics (according to the center's normal routine) and subsequently rinsed with 0.2% chlorhexidine solution for one minute. The surgical procedure was performed under local or under parenteral anesthesia. After flap elevation, a sealed randomization envelope was opened to allocate the subject to either one of the two treatment groups. In group short, 1-4 two-piece titanium dental implant(s) (ASTRA TECH Implant System OsseoSpeed™ 4.0S; DENTSPLY Implants, Mölndal, Sweden) with a length of 6mm and a diameter of 4mm was/were placed at the study site(s). In the group graft, a sinus floor elevation procedure using the lateral window technique (Boyne and James, 1980) was performed, followed by the placement of 1-4 two-piece titanium dental implant(s) (OsseoSpeed™ 4.0S; DENTSPLY Implants, Mölndal, Sweden) with a length of 11, 13 or 15mm and a diameter of 4mm. For the sinus elevation procedure, particulated bovine bone material (Bio-Oss granulate, Geistlich Pharma AG, Wolhusen, Switzerland) was used and a resorbable collagen membrane (Bio-Gide, Geistlich Pharma AG, Wolhusen, Switzerland) for the closure of the lateral window. In both groups in case of a small dehiscence, locally harvested autogenous bone chips were used to cover the exposed implant surface. No further bone substitute materials were applied. According to the protocol, implants were intended to be placed in a transmucosal manner. However, depending on the clinical situation and the surgeon's preference, the implants could be left for a submerged healing. A peri-apical x-ray of the implant site(s) was subsequently taken using the paralleling technique. Patients were instructed to rinse with 0.2% chlorhexidine solution (twice a day until suture removal) and were given antibiotics and analgesics (if needed).

Suture removal (SR)

Sutures were removed 7-14 days later. Any adverse events were recorded and a questionnaire (OHIP-49) was filled out by the patients.

Prosthetic procedures: impression (IM) and insertion of the final prosthetic reconstruction (PR)

Five months after implant placement (IP), an impression of the implant site(s) was taken and a final reconstruction fabricated. In case of a submerged healing, a minimally invasive abutment connection was performed at the same time (IM). Six to seven months after implant placement, the final prosthetic reconstruction was inserted. No restrictions were made regarding the material and the type of retention (screw-retained or cemented). However, all implants were reconstructed with single non-splinted crowns. Following insertion, a peri-apical x-ray was taken.

One-year follow-up (FU-1)

At FU-1 (1.5 years after implant placement and one year after prosthesis insertion), any adverse event was recorded, followed by a clinical examination with plaque (plaque control record=PCR) and bleeding on probing (BOP), as well as probing pocket depths (PPD) at four sites (mesial, distal, buccal, lingual) at the implant site(s) and the neighboring tooth site(s). An additional OHIP-49 questionnaire assessed the patient-reported outcomes measures. A peri-apical x-ray taken at this time-point was used to evaluate the marginal bone level.

Price calculations

In order to assess the price associated with both treatment modalities, the price for the surgical procedures for one single implant was calculated in all 5 participating centers. The ratio between the price for implant therapy with a short implant and the price for a sinus floor elevation procedure in combination with a long implant was calculated and then expressed as a percentage.

Patient-reported outcomes

Patient-reported outcomes were assessed using a standardized questionnaire (OHIP-49) handed to patients at baseline (SC), at suture removal (SR), at prosthesis insertion (PR) and at 1-year follow-up (FU-1). The OHIP-49 consists of 49 items divided into eight different dimensions. The patient responses indicated the frequency of the impact on the individual. This frequency ranged from “never” (score 0) to “very often” (score 4). Summing item responses were calculated generating dimensions scores (functional limitation questions (Q) 01-09, physical pain Q10-18, psychological discomfort Q19-23, physical disability Q24-32, physiological disability Q33-38, social disability Q39-43 and handicap Q44-49) and overall scores (Q01-49) for OHIP-49.

Safety

The safety assessment was performed reporting on adverse events (AEs)/adverse device effects (ADEs). An AE was defined as any untoward medical occurrence, unintended disease or injury or any untoward clinical sign in a subject, user or third party. The causality was categorized as being unrelated, possibly related or related. If an AE was categorized as being related to a medical device, then this event was considered to be an ADE. A serious adverse event (SAE) was an AE that fulfilled one or more of the following criteria: led to a death, led to a serious deterioration in the health of a subject (e.g. life-threatening illness or injury), led to fetal distress, fetal death or a congenital abnormality or birth defect. Finally, a serious adverse device effect (SADE) was defined as an ADE that was related to the medical device.

Statistical analysis

The statistical software used was IBM SPSS (IBM Corp., Armonk, NY), StatXact (Cytel, Cambridge, MA, USA) and Excel (Microsoft, Redmond, WA, USA). Prior to the start of the study, a sample size calculation was performed, based on comparing the proportion

of failed implants between the groups, i.e. implant is the statistical unit and primary outcome is failed/not-failed. A total of 125 implants per group to detect a difference in proportion of non-failed implants from 99% to 91% could be statistically detected with a power of about 80%. For calculation of the survival rate the two-sided exact 95% confidence interval for the difference between the proportions in the groups was calculated using the StatXact "unconditional procedure invert two one-sided tests". Exact binomial confidence intervals were calculated for the within group two-sided 95% confidence intervals. The OHIP-49 consists of 49 items divided into eight different dimensions. If an item was missing, the missing score was imputed by the mean of the non-missing scores within the dimension, given that at least 2/3 of the remaining items within the dimension were non-missing. A non-parametric statistical approach was applied because of the nature of the data. For continuous data the Wilcoxon Rank Sum test (exact) was used to compare treatment groups (Graft vs Short), Wilcoxon Signed Rank test (exact) was used to compare changes within each treatment group and Fisher's exact test for categorical data. A P-value below 0.05 was considered as statistically significant. No adjustment for multiplicity was applied.

RESULTS

The patient recruitment phase started in October 2009 and ended in February 2011. A total of 101 subjects entered the clinical trial (52 female, 49 male, mean age 50.5 years, range 20-75 years) fulfilling the inclusion criteria after screening and based on a clinical and radiographic examination (Figure 1). Fifty-one patients (70 implants) were allocated to group graft and 50 patients (67 implants) to group short. Figure 2 displays the location of the study sites and the respective number of implants. Out of 137 implants, 95% were placed in a transmucosal manner. Only 7 implants were submerged during the healing phase (2 in group short; 5 in group graft). Twenty-one percent of patients were smokers (16% in group short, 26% in group graft) and 25% previous smokers (20% and 29% respectively). Bruxism was only registered in one patient in group graft. Baseline demographics (e.g. age, gender, medical conditions, locations of implants, smoking habits) did not reveal statistically significant differences between the two groups. One patient in group short (2 implants) deceased prior to the day of impression (IM). Therefore, at prosthesis insertion, 100 patients with 135 implants were examined. Subsequently, one patient (group short with one implant) was lost to follow-up, while two more patients (one in group graft, one in group short; each patient with one implant) did not attend the one-year follow-up examination. All three patients refused to attend the follow-up examination. This resulted in 97 patients and 132 implants completing the 1-year follow-up. The 5 centers contributed with 26 patients (Switzerland), 24 patients (Austria), 20 patients (Poland), 16 patients (Spain) and 15 patients (USA).

Implant survival

All 132 implants in 97 patients examined at FU-1 were osseointegrated and clinically stable, thereby rendering a 100% implant survival rate. For the worst case scenario, all implants of patients not followed-up and therefore considered as being lost, the survival

rate for group graft is 98.6% (one implant considered as lost) and for group short 97.0% (two implants considered as lost) ($p>0.05$).

Duration of surgery

In group short (34 patients) the mean time needed to place one single implant amounted to 52.6 minutes (range 15-165 minutes). In group graft (36 patients) the additional sinus floor elevation procedure increased the surgery time by roughly 50%, rendering a mean of 74.6 minutes (range 20-210 minutes). The difference between the two groups was statistically significantly different ($p<0.05$).

Safety

A total number of 21 adverse events occurred (Table 7). In group graft, 1 out of 14 was considered serious (SAE), 2 causally possibly related to the device (CPAE), and 12 causally related to the device (CAE). In group short, these events accounted to 1 SAE, 2 CPAE, and 5 CAE. None of the SAEs was related to implant therapy. For a detailed overview on CAEs (17 events) see Table 8. The differences with respect to AEs were not statistically significant for the two groups on the subject level ($p>0.05$). One implant was mobile (spinner) at the day of impression. The healing abutment was removed and the implant retightened. One month later, the implant was osseointegrated again and the impression could be taken and the final crown be inserted.

Patient-reported outcomes measures

Mean OHIP-49 severity scores are displayed in Table 2 (SC), Table 3 (SR) and Table 4 (FU-1). None of the OHIP-49 dimensions revealed statistically significantly different mean severity scores between the two treatment modalities at SC, SR and FU-1 ($p>0.05$); except for physical pain in favor of group short at screening ($p<0.05$) (Tables 2-4).

P-values for changes between SR and SC are reported in Table 5 and between FU-1 and SC in Table 6. For these changes within the groups from baseline to suture removal

functional limitations and physical disability reached statistically significant differences in group graft ($p < 0.05$). In group short, p-values did not reach statistical significance over time ($p > 0.05$) (Table 5). Between the one-year follow-up and baseline, all OHIP dimensions reached statistical significance over time for both treatment modalities ($p < 0.05$), except for social disability in group graft ($p > 0.05$) (Table 6).

Price of treatments

The price of both treatment modalities was calculated for one single implant limited to the surgery (without prosthetic treatment). The mean price for group short amounted to 941 EUR (range 626 – 1313 EUR); while in group graft the mean price was 1946 EUR (range 1455 – 2691 EUR). The calculated ratio (short implant/sinus grafting) ranged between 43% and 54% (mean=48%; SD=3.5%).

DISCUSSION

This multi-center randomized controlled clinical trial demonstrated both treatments to be safe and successful during the observation period of 1 year of loading with single crowns. Implant survival rates were similar in both groups (100%). Short implants, however, reduced the treatment price, the surgical time and the postoperative patient morbidity.

Financial aspects are important parts of the initial treatment planning beside other factors such as expected complications, success rates, potential biological and esthetic risks. Depending on the individual healthcare system of the respective country, the price of implant therapy may have to be provided by patients and may decide on whether or not a specific therapy will be carried out or not (Kalsi and Hemmings, 2013). Generally speaking, two treatments rendering similar long-term outcomes, the more cost-effective treatment option appears more appropriate. Cost-benefit calculations have been performed for single tooth replacements and concluded that beside initial costs, follow-up costs need to be taken into consideration. Besides lower initial costs, reparations and potential replacements may be a major cost factor and influence the decision for a specific therapy (Zitzmann et al., 2013, Bragger et al., 2005, Leung and McGrath, 2010). In a randomized controlled clinical trial with a split-mouth design, two treatment options (sinus floor elevation and staged implant placement or short dental implants) were compared (Esposito et al., 2011b). The study indicated that treatment costs were in favor of the group with short dental implants at 1 year (Esposito et al., 2011b) and 3 years of loading (Esposito et al., 2011a). This is in line with the outcomes of the present study, demonstrating an increase in treatment price of a 100% for group graft. However, as mentioned above, these price calculations only include initial costs and long-term results are needed to make more precise recommendations for either one therapy.

The measured **surgical time** to place one single dental implant with or without simultaneous sinus floor elevation was in favor of short implants, but demonstrated, however, a great variation within and between the centers. The sinus floor elevation procedure in combination with the placement of longer implants increased the surgery time by roughly 50%. Previous studies have indicated a correlation between surgical time and complications reported by patients. In a clinical study, the prevalence of post-surgical complications was evaluated in a large population undergoing different surgical procedures (Tan et al., 2014). Patient-reported outcome measures (PROMs) were assessed regarding bleeding, swelling, pain and bruising using Visual Analogue Scales (VAS) on days 0, 3, 5 and 7 post-operatively. For implant therapy, shorter surgical duration was associated with lower VAS scores in PROM parameters in this patient population. When comparing different treatment options in a given clinical situation, it is important to not only assess traditional clinical and radiographic parameters but also to assess PROMs. Only the combination of these assessment methods allows a comprehensive comparison and evaluation of different treatment options.

Previous data revealed that surgical time depends on the experience of the surgeon. In addition, inexperienced surgeons have been reported to have twice as many implant failures compared to experienced ones (Truhlar et al., 1994). Compared to standard implant placement, sinus floor elevation procedures require advanced surgical skills. Furthermore, in such cases two surgical steps are necessary: sinus floor elevation and implant placement. Therefore, complication rates may increase compared to the procedure of standard implant placement.

A way to express such PROMs is through questionnaires filled out by patients at different time-points during implant therapy. For that purpose in the present study, an **OHIP** questionnaire was used. The OHIP was originally developed to assess oral health and to account for limitations in terms of dysfunction, discomfort and disability associated with oral disorders (Slade and Spencer, 1994). Various OHIP forms have been used and are classified by the number of included questions. In this study, an

OHIP-49 was applied. This index assessed PROMs at and between different time-points. Most importantly and interestingly were the mean changes in severity scores between baseline and suture removal. The results demonstrated that mean severity scores were higher at suture removal compared to baseline and insertion of the final reconstruction, for both groups. This indicates that both surgical procedures had an impact on patient's quality of life during the first 7-14 days after surgery. In contrast, during the following months, quality of life was experienced at a level similar to baseline. In addition, p-values demonstrated a significant decrease in mean OHIP severity scores predominantly for group graft, thereby indicating that the additional procedure of a sinus floor elevation concomitant with the placement of a longer implant does indeed affect patient's quality of life. OHIP questionnaires were earlier used to assess the effect of implant therapy on patient's quality of life comparing before and after treatment (Zembic and Wismeijer, 2014, Mundt et al., 2013, Gates et al., 2014, Awad et al., 2003). However, the literature is scarce with respect to the comparison of patient morbidity, when applying two treatment modalities with dental implants. In a clinical study, OHIP-49 questionnaires were used to assess PROMs comparing autogenous bone harvesting from intra- or extraoral sites. At 3 days following surgery, mean severity scores primarily of the physical dimension, differed between the two groups and were higher compared to baseline (Reissmann et al., 2013). The results of the present study are in agreement with these data indicating that patient's quality of life is primarily affected short term following surgical interventions.

Besides the fact that OHIP scores increased due to the surgical intervention, a number of **AEs** occurred during the 1.5-year observation period. Except for the two SAEs that were unrelated to implant therapy, a number of AEs was related to the medical device or the surgery. In group graft, the overall higher number of AEs was predominantly associated with postoperative complications, since they were mainly registered at or between implant placement and suture removal. This further underlines that a sinus floor elevation concomitant with the placement of a longer implant causes a higher

number of short-term complications, but thereafter and within the observation period, both treatment modalities are safe and predictable. The amount of AEs reported (21 in 101 patients, resulting in roughly 20% rate of complications) is in agreement with previous studies on sinus grafting and concomitant implant placement. In one particular study, 15% of the patients developed postoperative complications following sinus grafting with simultaneous or staged implant placement (Moreno Vazquez et al., 2014), whereas the rate of complications (14) exceeded the number of included patients (12) in another study (Pistilli et al., 2013). In the latter study, the control group (short implants, no sinus augmentation) did not show any complications prior to loading. The comparatively increased rate of complications in the present study is mainly due to the fact, that AEs were also reported for the loading period. This time-period accounted for 6 AEs mainly consisting of prosthetically related complications (fracture of abutment screws, screw loosening).

The results of this study demonstrate similar survival rates, but differences in terms of patient-reported outcomes, surgical time and cost analysis. Even though, this multicenter study was highly standardized with respect to the two surgical interventions, a number of limitations apply and included: i) a possible center-effect; ii) an imbalance regarding the number of included patients at each center; iii) no restrictions with respect to the type of medication including anesthesia, the healing mode and the prosthetic protocol; iv) a lower number of implants (132 implants were included resulting in a statistical power of around 56%) compared to the initially anticipated number to be included based on the sample size calculation. Since this multicenter study primarily focused on the survival rates of the two groups and patient-reported outcomes and since a high number of patients and implants were included, some of these limitations may have been partially overcome by the randomization process.

CONCLUSIONS

Within the limitations of this study it can be concluded that: i) both treatment modalities are safe and successful rendering a high implant survival rate; ii) patient morbidity was increased due to the surgical intervention short-term in both groups (7-14 days after implant placement); iii) group graft demonstrated a significant decrease in OHIP dimensions between suture removal and baseline, but not group short; iv) surgical time to place one single implant was 100% longer in group graft compared to group short; v) the price of the treatment for one single implant was 100% higher in group graft compared to group short; vi) longer-term data are mandatory in order to make a more comprehensive comparison of the two treatment modalities under investigation.

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FIGURE LEGENDS

Figure 1: Flow-chart depicting visits, time-line and included patients.

Figure 2: Location and number of implants placed.

Table 1: Performed interventions at study-related time-points. OHIP=oral health impact profile; BOP=bleeding on probing; PPD=periodontal probing depth; PCR=plaque control record; AE=adverse event; ADE=adverse device effects.

Table 2a: Mean OHIP-49 scores for each of the eight dimensions at screening (SC)

Table 2b: Mean OHIP-49 scores for each of the eight dimensions at suture removal (SR)

Table 2c: Mean OHIP-49 scores for each of the eight dimensions at the 1-year follow-up (FU-1)

Table 2d: P-values for mean OHIP-49 score changes between suture removal (SR) and Screening (SC) for both treatment modalities. Questions that were not applicable (N/A) were recoded as „never“. P-values were calculated for change over time within groups and for the overall change (all patients included).

Table 2e: P-values for mean OHIP-49 score changes between 1-year follow-up (FU-1) and Screening (SC). Questions that were not applicable (N/A) were recoded as „never“. P-values were calculated for change over time within groups and for the overall change (all patients included).

Table 3: Summary of adverse events (AE) reported for both treatment modalities and in total.

Table 4: Summary of adverse device effects (ADE) reported for both treatment modalities and in total.

Figures and Tables

Figure 1

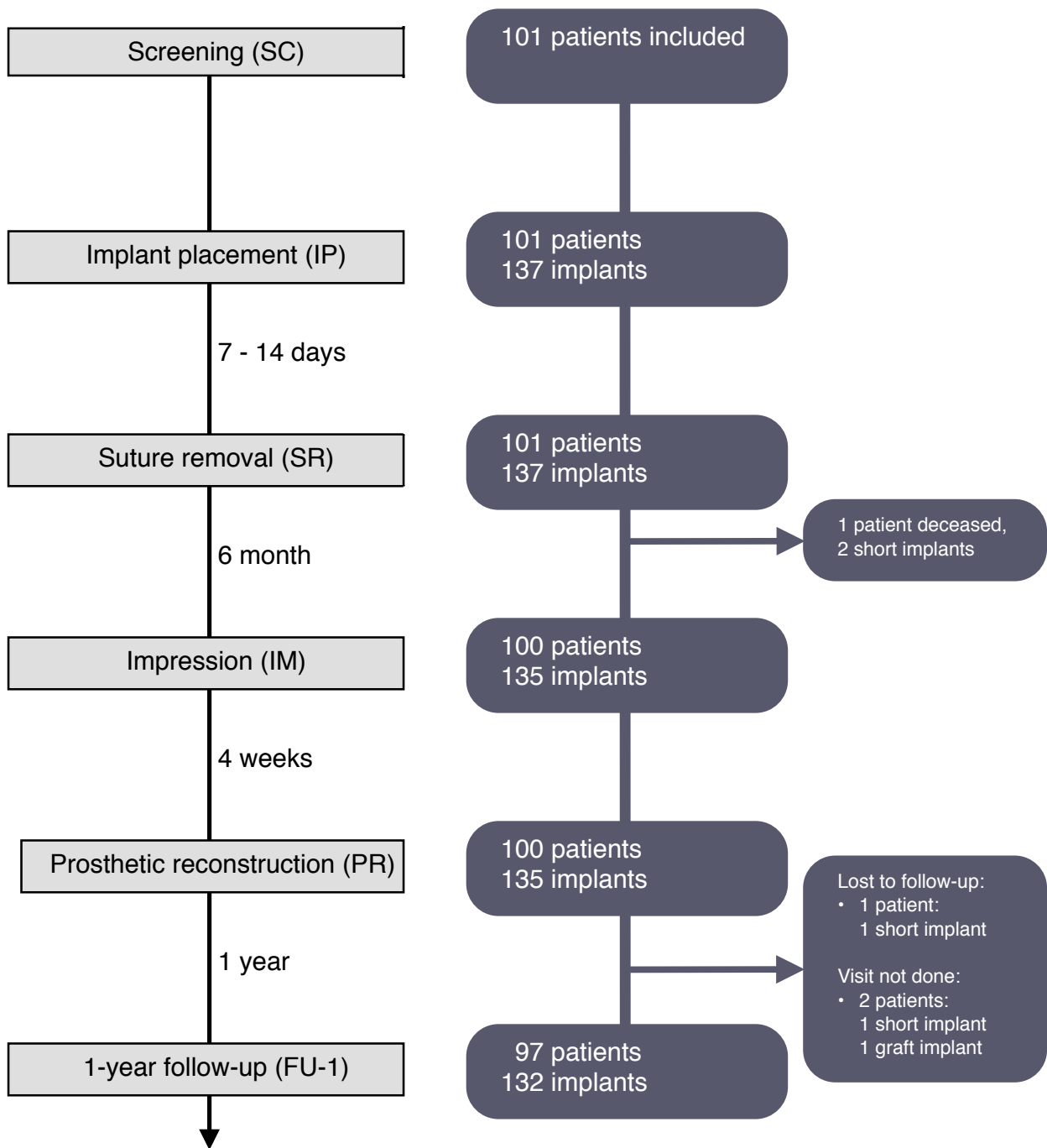


Figure 2

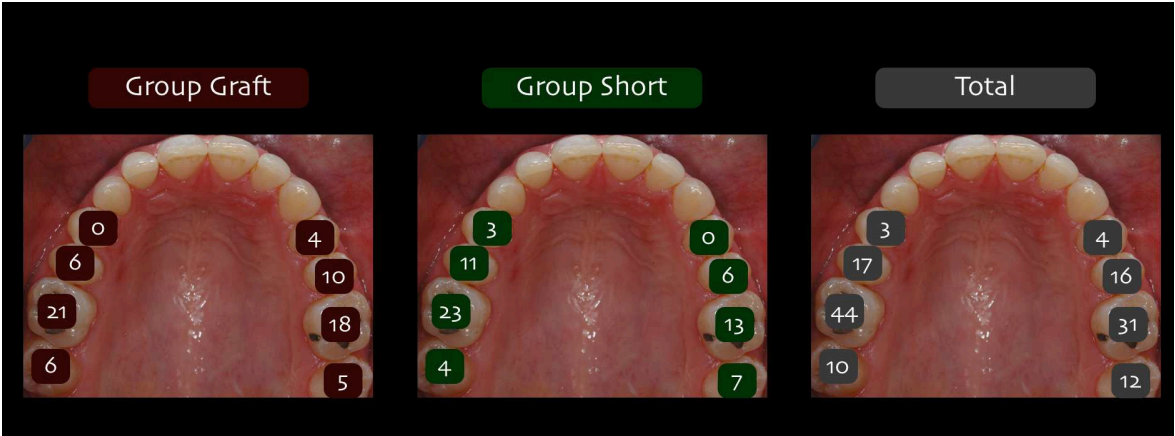


Table 1

	Screening (SC)	Implant placement (IP)	Suture removal (SR)	Impression (IM)	Insertion of prosthetic reconstruction (PR)	1-year follow- up (FU-1)
Informed consent	x					
Subject demographics	x					
Medical/Surgical history	x					
Inclusion/Exclusion criteria	x					
Oral examination	x					
Randomization		x				
Radiographic examination	x	x			x	x
OHIP-49	x		x		x	x
Condition of periimplant mucosa (BOP, PPD)						x
Plaque control records (PCR)						x
Health economics	x	x				
AE/ADE		x	x	x	x	x
Implant stability		x		x	x	x
Clinical photography	x	x	x	x	x	x

Table 2a

		Group Graft (n=40) Mean score ± SD	Group Short (n=40) Mean score ± SD	Difference in mean scores	p-value
1	Functional limitation Q01-09	9.11 ± 7.24	6.23 ± 6.48	2.88	0.0340
2	Physical pain Q10-18	8.05 ± 4.99	5.23 ± 6.14	2.82	0.0031
3	Psychological discomfort Q19-23	5.05 ± 5.41	4.80 ± 5.57	0.25	0.7674
4	Physical disability Q24-32	3.88 ± 4.82	3.45 ± 5.81	0.43	0.3058
5	Physiological disability Q33-38	3.51 ± 4.04	3.00 ± 4.53	0.51	0.2076
6	Social disability Q39-43	1.08 ± 2.64	1.13 ± 2.65	-0.05	0.9969
7	Handicap Q44-49	2.18 ± 3.54	1.82 ± 3.52	0.36	0.2341
8	Overall Q01-49	32.78 ± 27.79	26.27 ± 30.28	6.51	0.1072

Table 2b

		Group Graft (n=40) Mean score ± SD	Group Short (n=40) Mean score ± SD	Difference in mean scores	p-value
1	Functional limitation Q01-09	7.64 ± 7.15	5.52 ± 5.95	2.12	0.1112
2	Physical pain Q10-18	9.10 ± 8.00	6.55 ± 6.83	2.55	0.0942
3	Psychological discomfort Q19-23	4.10 ± 5.41	4.60 ± 5.76	-0.50	0.9585
4	Physical disability Q24-32	6.27 ± 7.60	4.28 ± 5.34	1.99	0.3247
5	Physiological disability Q33-38	3.18 ± 5.01	2.95 ± 4.27	0.23	0.9897
6	Social disability Q39-43	2.05 ± 3.92	1.23 ± 2.67	0.82	0.7340
7	Handicap Q44-49	2.51 ± 4.67	2.00 ± 3.46	0.51	0.5192
8	Overall Q01-49	31.70 ± 34.01	27.15 ± 29.87	4.55	0.3624

Table 2c

		Group Graft (n=38) Mean score ± SD	Group Short (n=37) Mean score ± SD	Difference in mean scores	p-value
1	Functional limitation Q01-09	4.35 ± 4.05	3.53 ± 4.13	0.82	0.2070
2	Physical pain Q10-18	4.44 ± 4.35	3.58 ± 4.41	0.86	0.3240
3	Psychological discomfort Q19-23	1.84 ± 3.27	2.03 ± 3.35	-0.19	0.9812
4	Physical disability Q24-32	1.71 ± 2.79	2.24 ± 3.63	-0.53	0.7300
5	Physiological disability Q33-38	1.03 ± 2.43	1.48 ± 2.49	-0.45	0.1487
6	Social disability Q39-43	1.67 ± 0.00	0.67 ± 3.00	1.00	0.5010
7	Handicap Q44-49	1.03 ± 2.50	0.82 ± 1.59	0.21	0.7184
8	Overall Q01-49	15.80 ± 18.13	14.22 ± 17.54	1.58	0.2472

Table 2d

		Group Graft	Group Short	Overall
1	Functional limitation Q01-09	0.0320	0.2488	0.0159
2	Physical pain Q10-18	0.9375	0.1648	0.3910
3	Psychological discomfort Q19-23	0.2248	0.3154	0.1223
4	Physical disability Q24-32	0.0073	0.1061	0.0028
5	Physiological disability Q33-38	0.2073	0.6613	0.2040
6	Social disability Q39-43	0.0646	0.6489	0.0674
7	Handicap Q44-49	0.7470	0.4908	0.4600
8	Overall Q01-49	0.7948	0.9709	0.8709

Table 2e

		Group Graft	Group Short	Overall
1	Functional limitation Q01-09	0.0000	0.0036	0.0000
2	Physical pain Q10-18	0.0000	0.0419	0.0000
3	Psychological discomfort Q19-23	0.0004	0.0044	0.0000
4	Physical disability Q24-32	0.0069	0.0421	0.0007
5	Physiological disability Q33-38	0.0000	0.0099	0.0000
6	Social disability Q39-43	0.1484	0.0332	0.0054
7	Handicap Q44-49	0.0093	0.0278	0.0005
8	Overall Q01-49	0.0000	0.0019	0.0000

Table 3

	Group Graft	Group Short	Total
No. of AE	14	7	21
SAEs	1	1	2
AE causally possibly related to the medical device	2	2	4
AE causally related to the medical device	12	5	17

Table 4

	Group Graft	Group Short	Total
Abutment loose	2	1	3
Abutment other	1	1	2
Implant mobile	1		1
Pronounced hematoma	1		1
Buccal fistula mesial border of flap incision	1		1
Surgically related	6	2	8
Fracture screw abutment		1	1
Total	12	5	17